JUN 1 2 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS K 000072
Dornier Surgical Products, Inc.'s *Medilas D SkinPulse* Laser

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Dornier *Medilas D SkinPulse* Laser is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which includes the following: Dornier *Medilas D* Laser System (K982629) and Candela GentleLase II Dermatological Laser (K984601).

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Dornier Surgical Products, Inc.
10027 South 51st Street
Phoenix, AZ 85044
Contact Person: Suzanne Courtney

Phone: 770-693-5793
Facsimile: 770-693-5770

Date Prepared: May 31, 2000

Name of Device and Name/Address of Sponsor

Dornier *Medilas D SkinPulse* Laser
Dornier Surgical Products, Inc.
10027 South 51st Street
Phoenix, AZ 85044

Classification Name

Diode lasers have not been specifically classified by FDA.

Predicate Devices

- Dornier *Medilas D* Laser System (K982629)
- Candela GentleLase II Dermatological Laser (K984601)

Intended Use

The Dornier *Medilas D SkinPulse* Laser is intended for use in cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or in incision/excision, vaporization, ablation and coagulation of soft tissue in contact or non-contact open surgery (with or without a handpiece). The *SkinPulse* laser is also for use for the treatment and/or removal of vascular lesions.

The Dornier *Medilas D SkinPulse* Laser is indicated for use in medicine and surgery, in the following specialties: Urology, Plastic Surgery, Dermatology, Radiology, Pulmonology, Gastroenterology, Gynecology, ENT, and General Surgery.

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the Dornier Medilas D laser and the predicate devices are substantially equivalent and have the same intended use. Based on the technological characteristics and overall performance of the devices, Dornier Surgical Products, Inc. believes that no significant differences exist between the Dornier Medilas D and the predicate devices, Dornier *Medilas D* Laser System (K982629) and Candela GentleLase II Dermatological Laser (K984601).

Dornier Surgical Products, Inc. believes the minor differences of the Dornier Medilas D and its predicate laser devices should not raise any concerns regarding the overall safety or effectiveness.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2000

Ms. Suzanne Courtney
Regulatory Specialist
Dornier Surgical Products, Inc.
955 Covv Place, Suite 200
Kennesaw, Georgia 30144

Re: K000072
Trade Name: Medilas D SkinPulse Laser
Regulatory Class: II
Product Code: GEX
Dated: May 4, 2000
Received: May 8, 2000

Dear Ms. Courtney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K000072

Device Name: Dornier *Medilas D SkinPulse* Laser

Indications for Use:

The Dornier *Medilas D SkinPulse* Laser is intended for use in cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or in incision/excision, vaporization, ablation and coagulation of soft tissue in contact or non-contact open surgery (with or without a handpiece). The *SkinPulse* laser is also for use for the treatment and/or removal of vascular lesions.

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- Urology
- Plastic Surgery
- Dermatology
- Radiology
- Pulmonology
- Gastroenterology
- Gynecology
- ENT
- General Surgery

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use _____

Diane R. Vachon

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000072